K032716

NOV 2 8 2003

Portex Ltd. Thermovent HEPA HME Breathing Filter with CO_2 port.
510(K) Notification

SECTION 5.0 : 510K SUMMARY

DATE SUBMITTED: 26th August 2003

SUBMITTER:
Portex Ltd
Hythe
Kent
England, CT21 6JL

CONTACT PERSON:
Mr Steve Ogilvie,
Regulatory and Scientific Affairs Director,
Portex Ltd,
Military Road,
Hythe, Kent, England. CT21 6DB
Phone 00 44 (0)1303 260551
Fax 00 44 (0)1303 262798

DEVICE NAME: Portex Thermovent HEPA HME Breathing System Filter with CO_2 port

COMMON NAME AND CLASSIFICATION: Bacterial/Viral filter and Heat and Moisture Exchanger (HME) Class II, 73 CAH, CFR 868.5260

PREDICATE DEVICES:

- Pall BB25 Small Volume HME filter with monitoring port, already marketed in the USA under Pre-market Notification No.K791307 (Trade name – Pall Ultipor 25 breathing system filter)
- Porous Media Corporation DBF23 Bacterial/Viral filter already marketed in the USA under Pre-market Notification No.K964979

DEVICE DESCRIPTION:

The Thermovent HEPA (High Efficiency Particulate Air) HME (Heat and Moisture Exchange) breathing system filter is a single use bacterial and viral filter with 'HEPA' grade filtration properties. The filter is intended for use with ventilators, anaesthesia breathing circuits, positive breathing systems and passive spontaneous breathing intubated patients.

The Thermovent HEPA is a hydrophobic filter, which acts as an effective barrier to both air and liquid borne contaminates. The filter media repels liquid and therefore prevents any liquid moving from the patient side of the device through to the ventilator circuit. To maximise the filtration surface area, the filter media is pleated before assembly into the filter housing.

The Thermovent HEPA also acts as a passive, hydrophobic humidifier. The expired gasses from the patient condense on the surface of the media, while releasing latent heat and warming the filter element. On inspiration, the airflow is warmed by the filter element, while the liquefied water is vaporised, thus allowing humidified air to be returned to the patient.

Portex Ltd. Thermovent HEPA HME Breathing Filter with CO_2 port.
510(K) Notification

SECTION 5.0 : 510K SUMMARY

The Thermovent HEPA has a Luer port on the machine side of the housing to allow monitoring of the patients gasses, after filtration. The filter housing also features a peg where the user can park the cap when the gas sampling port is in use.

The devices are packed individually in flexible thermoformed pouch type unit packs.

INTENDED USE:

The Thermovent HEPA HME breathing system filter provides bacterial and viral filtration protecting the patient and the breathing circuit or ventilator. It also provides passive heat and humidification to the patient.

TECHNOLOGICAL CHARACTERISTICS OF PROPOSED VERSUS PREDICATE DEVICES:

- The proposed device is substantially equivalent to Predicate device 1 - Pall BB25 Small Volume HME filter with monitoring port, (Pre-market Notification No.K791307) in all aspects except the following:
    - Differences in filter internal volumes (dead space) as listed in section 7, Table 4. The instructions for use for the proposed device prescribe that the acceptability of the filter's dead space be evaluated on an individual patient basis.

PERFORMANCE / CLINICAL DATA:

Performance data for the proposed device is shown in section 8.0 Performance.

NONCLINICAL TESTING FOR THE DEVICE AND CONCLUSIONS:

- The proposed device complies with the standards below and is therefore safe and effective for the intended use. The proposed device has been tested through validation and verification of specifications. Verification of compliance with the following voluntary standards has been conducted.
    - ISO 23328-1:Draft, BS EN 13328-1:2001 Breathing system filters for anaesthetic and respiratory use. Salt test method to assess filtration performance
    - ISO 23328-2:2002, BS EN 13328-2:2002 Breathing system filters for anaesthesia and respiratory use. Non-filtration aspects
    - BS EN ISO 9360-1:2000 Anaesthetic and Respiratory Equipment – Heat and moisture exchanges for use in humidifying respired gases in humans.
    - ISO 594-2:1998, BS EN 20594-2:1994 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings.
    - ISO 5356-1: 1996, BS EN 1281-1:1997 Anaesthetic and Respiratory Equipment – Conical Connectors , Part 1: Cones and Sockets
    - Code of Federal Regulations, Title 42, Volume 1 Part 84--Approval of Respiratory Protective Devices

CONCLUSION:

Comparison of the proposed device to the predicate device supports the conclusion that the proposed device is substantially equivalent in safety and effectiveness in its intended use to the existing legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2003

Mr. Steve Ogilvie
Portex LTD
Military Road
Hythe Kent
CT21 6JL England

Re: K032716
Trade/Device Name: Thermovent HEPA HME Breathing Filter, Sterile
Thermovent HEPA HME Breathing Filter, Non-sterile
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: II
Product Code: CAH
Dated: August 26, 2003
Received: September 2, 2003

Dear Mr. Ogilvie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html .

Sincerely yours,

Michael Szarf for:

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Portex Ltd. Thermovent HEPA HME Breathing Filter with CO_2 port.
510(K) Notification

SECTION 4.0: STATEMENT OF INDICATIONS FOR USE

K032716

GENERAL DESCRIPTION OF USE:

The Portex Thermovent HEPA (High Efficiency Particulate) is a single use heat and moisture exchanging (HME) bacterial/viral breathing system filter with 'HEPA' grade filtration properties.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☑ OR Over The Counter Use

CFR 801.109

M. Segal 11/20/03

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032716